

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference P-6867-PC	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IL2004/000532	International filing date (<i>day/month/year</i>) 17 June 2004 (17.06.2004)	Priority date (<i>day/month/year</i>) 20 June 2003 (20.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant NUTRINIA LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 Form PCT/IB/373 (January 2004)	Date of issuance of this report 03 January 2006 (03.01.2006)
	Authorized officer Simin Baharluu Telephone No. +41 22 338 71 30

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 05 OCT 2005

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WIPO

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To:
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

03 OCT 2005

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference

P-6867-PC

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/IL04/00532

17 June 2004 (17.06.2004)

20 June 2003 (20.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A23C 9/20 and US Cl.: 426/585

Applicant

NUTRINIA LTD

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(f) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL04/00532

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 12-15, 17-19, 51-52, 56, 71 YES

Claims 1-11, 16, 20-50, 53-55, 57-70, 72-87 NO

Inventive step (IS)

Claims NONE YES

Claims 1-87 NO

Industrial applicability (IA)

Claims 1-87 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL04/00532

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-11, 16, 20-50, 53-55, 57-70, 72-87 lack novelty under PCT Article 33(2) as being anticipated by RUBIN US 5013569.

RUBIN teaches a method of encapsulating bioactive materials such as immunoglobulins and omega-3 fatty acids and fortifying infant formula with the composition. Various methods for micro encapsulation are disclosed, such as forming micelles in water-in-oil emulsions, spray drying to make fine particles, decreasing the solubility of a polymeric solution to induce coacervation, modifying the temperature of a polymeric solution until the polymer is no longer soluble and precipitates, interfacial polymerization, or the capsules can be formed in a dry blending process using free-flowable inclusion compounds such as cyclodextrins. This anticipates the "grinding a dry blend" limitation because in order for a powder mixture to be free flowable it must be ground to make them fine particles. The particles disclosed, sizes 80-300 nm, or 250 microns, resulting from the methods of encapsulation disclosed, anticipate instant claims to the particle sizes of the microcapsules. RUBIN further teaches the infant formulation can be in the form of a concentrated powder or liquid, or in a ready to use form. RUBIN teaches the inclusion of feed or food grade materials in the composition such as edible fats, non-fat milk, peanut oil, soybean oil, whey, sugars, vitamins and minerals. RUBIN discloses that acid milk whey contains beta lactoglobulins, immunoglobulins, and serum albumin. The formulation of the infant formula is intended to mimic human mother's milk. Humans are primates, this teaching therefore anticipates instant claims. The method also includes administering the formula composition to premature infants. Human milk is beneficial to human infants and a composition with added immunoglobulins will help boost the infants immunity, which would improve the health status of an infant. Therefore the instant claims are anticipated.

Claims 1-87 lack an inventive step under PCT Article 33(3) as being obvious over RUBIN US 5013569 in view of PAUL US 5531989. The limitations taught by RUBIN are discussed above.

PAUL teaches the same ingredients for the production of a concentrate that contains milk protein, immunoglobulins, fiber, and other feed/food grade materials. PAUL teaches the use of carbohydrates such as maltodextrin in the composition, and the source of the immunoglobulin from milk products and whey. The immunoglobulin concentrate is formed by freeze-drying or spray drying methods. Paul teaches the composition can be reconstituted in water or other liquids. PAUL teaches the incorporation of other bioactive compounds such as insulin in the composition.

It would be obvious to one of ordinary skill to incorporate the maltodextrin taught by PAUL in the microencapsulating process taught by RUBIN because PAUL teaches the same ingredients as RUBIN and also teaches a concentrate formulation. It would also be obvious to use freeze-drying and spray drying techniques in formation of the product because both RUBIN and PAUL teach this process.

Claims 1-87 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of JANDA et al. US 5418010.

JANDA further teaches that spray drying and extrusion are processes widely used by those of ordinary skill in the art for microencapsulating processes.

It would be obvious to one of ordinary skill in the art to employ these methods in forming microencapsulated particles for incorporation in infant formula because JANDA teaches that these processes are well known in the art. Also RUBIN discloses a variety of methods are

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

possible for the preparation of microencapsulated particles.

Claims 12-15, 17-19, 51-52, 56, 71 meet the criteria set out in PCT Article 33(2), because the prior art does not teach the exact limitations as set forth in the instant claims.

Claims 1-87 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.